DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 21, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-89

Steven E. Fick, Owner
Fish Hawk Fisheries, Inc.
Foot of 4th and Water
Astoria, Oregon 97103

WARNING LETTER

Dear Mr. Fick:

We inspected your firm located at Foot of 4th and Water, Astoria, Oregon, on May 31 through June 2, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your cooked ready to eat shrimp to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviation found was as follows:

> You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). Your firm did not take a corrective action to control pathogen survival when your process for shrimp deviated from your critical limit at the cooking critical control point. On your cooking log for May 17, 18, 24, 25, and 26, 2000, your cooking temperature never reached above 184°F where your HACCP plan states the shrimp cook at [redacted]°F for [redacted].
>
> A sample of fresh cooked and peeled shrimp was collected from the processing line during the inspection on May 31 through June 2, 2000. Analysis of the sample found *Listeria monocytogenes* type 4 in one composite, prepared from five different subsamples, and *Listeria innocua* detected in a second composite, prepared from five different subsamples. It is your responsibility to assure your process will produce a finished product free of pathogens.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: OSDA with disclosure statement